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TRANSMITTAL FORM

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Total Number of Pages in This Submission	7

Application Number	09/545,772
Filing Date	April 10, 2000
First Named Inventor	Tracy D. WILKINS
Art Unit	1645
Examiner Name	V. Ford
Attorney Docket Number	420522000100

ENCLOSURES (*Check all that apply*)

- [ ] Fee Transmittal Form
- [ ] Fee Attached
- [ ] Amendment/Reply
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
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- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
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- [ ] Petition to Convert to a Provisional Application
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- [ ] Terminal Disclaimer
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- [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [x] Appeal Communication to Board of Appeals and Interferences (Reply Brief) (6 pages)
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	MORRISON & FOERSTER LLP		
Signature			
Printed name	Carolyn A. Favorito		
Date	June 23, 2006	Reg. No.	39,183

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: June 23, 2006 Signature: _____ (Germaine Sarda)

sd-322935

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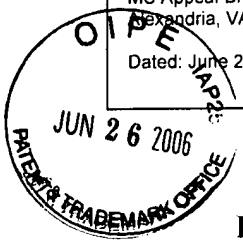
Dated: June 23, 2006 Signature: (Germaine Sarda)



Docket No.: 420522000100
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
Tracy D. WILKINS et al.

Application No.: 09/545,772 Confirmation No.: 3347

Filed: April 10, 2000 Art Unit: 1645

For: RECOMBINANT TOXIN A PROTEIN CARRIER FOR POLYSACCHARIDE CONJUGATE VACCINES Examiner: V. Ford

REPLY BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This reply responds to the Examiner's Answer mailed April 24, 2006. A response is due June 24, 2006. Thus, this Reply Brief is timely filed.

sd-322075

I. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether *prima facie* obviousness under 35 U.S.C. § 103 has been established for

1) claims 1, 3, 6, 13-15, 19-20, 23-24, and 36-39 based on Thomas in view of Schneerson *et al.* (Schneerson);

2) claims 1, 3, 6, 13-15, 19-20, 25-26, and 36-39, based on Thomas in view of Taylor *et al.* (Taylor);

3) claims 1, 3, 6, 13-15, 19-20, 28-29, 36-39 and 62 based on Thomas in view of Devi *et al.* (Devi); and

4) claims 1, 3, 6, 13-15, 19, 30-31, 33, and 36-39 based on Thomas in view of Fattom, *et al.* (Fattom).

II. ARGUMENTS IN RESPONSE TO EXAMINER'S ANSWER

A. The Examiner Erred in her Characterization of the Secondary References

First, the Examiner has erred in her characterization of Schneerson. The Examiner alleges that the Schneerson demonstrates that 14 *Streptococcus pneumoniae* capsular polysaccharides are poorly immunogenic and conjugating these capsular polysaccharides to carrier proteins enhances their immunogenicity. Appellants respectfully submit that Schneerson does not demonstrate that conjugating capsular polysaccharides to *any* carrier protein enhances their immunogenicity. Rather, Schneerson discloses conjugating a particular capsular polysaccharide to a particular carrier protein, pertussis toxin.

In fact, Schneerson references a document which discloses that routes of injection for conjugates were not suitable for humans. Please see Robbins, et al., *J. Infect.* 821-832, 822 (1990). The present claims refer to compositions which are formulated for injection and thus, this reference confirms that not any carrier protein is appropriate.

Robbins was cited in the PTO-892 attached to the Office Action mailed November 26, 2001, however, a copy is attached to the Reply Brief as Appendix A for the convenience of the Board. Thus, Schneerson does not disclose that all carrier proteins enhance the immunogenicity of polysaccharides, but rather merely discloses that the *Streptococcus pneumoniae* capsular polysaccharide conjugated to pertussis toxin elicited protective antibodies.

Second, the Examiner erred in her characterization of Taylor when she alleged that "Taylor et al. have demonstrated that polysaccharides [are] poorly immunogenic when administered alone and immunogenicity is enhanced when coupled to a carrier protein..." Please see page 14, lines 7-9 of the Answer. This similarly implies that any carrier protein will do. Taylor only discloses a conjugate containing O-specific polysaccharides of *Shingella dysenteriae* and recombinant *Pseudomonas aeruginosa* exoprotein A or tetanus toxoid. Please see Taylor, page 3679, right column, first paragraph.

Third, the Examiner erred in her characterization of Devi. Similarly, Devi does not demonstrate that the polysaccharides disclosed therein have enhanced immunogenicity when coupled to all carrier proteins but rather only with the specific protein, tetanus toxoid.

Finally, the Examiner has erred in her characterization of Fattom because Fattom does not demonstrate that the polysaccharides disclosed therein have enhanced immunogenicity when coupled to any carrier protein but rather only when conjugated to the entire endotoxin A protein.

Thus, none of the secondary references suggest coupling the polysaccharide to all carrier proteins will enhance the immunogenicity of the polysaccharides. No motivation in these references has been provided to select rARU and combine it with any of the polysaccharides disclosed in Schneerson, Taylor, Devi or Fattom to arrive at a combination suitable for injection.

B. The Examiner Erred by Not Providing Motivation to Select the Claimed Species

Thomas does not disclose polysaccharide antigens. The whole of Thomas's disclosure directs one to select *protein* antigens such as urease, or ovalbumin, not polysaccharide antigens. Further, as described in section A, above, there is no motivation in the secondary references to select and combine the polysaccharide antigens disclosed therein with *r*ARU.

Furthermore, there is no motivation to select non-*C. difficile* polysaccharides antigens as claimed. Thomas discloses in column 2, lines 63-64 that antigens may be derived from fragments or *C. difficile*. Further, there is no motivation to select rARU from *C. difficile* from the myriad of carrier or adjuvants disclosed in Thomas, which include *C. difficile,* Toxin A, Toxin B or fragments or mutants thereof, or toxins from *C. novyi, C. sordelli, C. perfringens, C. tetani,* or *C. batulinum,* or GST-ARU.

Also, although Thomas generally discusses compositions which may be injected, there is no specific description for injecting compositions where *r*ARU is the carrier. As such, a skilled artisan would not be led to select such a species.

Thus, the Examiner erred by not providing the requisite motivation to select the compounds to arrive at the claimed species.

C. The Examiner Erred by Not Establishing a Reasonable Expectation of Success.

The Examiner alleges (page 22, lines 11-15 of the Examiner's Answer) that "*any* antigen" (emphasis added) can be administered with the rARU adjuvant and Schneerson "has demonstrated success in conjugating polysaccharides to carrier proteins." However, the Examiner has not established that there is a reasonable expectation that the claimed combination would have a reasonable expectation of successful especially in light of the disclosure in Robbins described above.

D. Request to Withdraw Issue Relating to Finality

Appellants respectfully request the Board to withdraw the issue in item 6a) in the Appeal Brief filed July 30, 2004 regarding the finality of the Office action. This issue may not be advanced as a ground for appeal under MPEP § 706.07(c).

III. CONCLUSION

Appellants respectfully submit that the Examiner erred in establishing all of the elements necessary to establish *prima facie* obviousness. Particularly, the Examiner has not provided the motivation to select and combine the components of the cited references to arrive at the claimed invention, and has not established that such a combination would have a reasonable expectation of success.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, appellants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 420522000100.

Dated: June 23, 2006

Respectfully submitted,

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